

REMARKS

The present invention relates to methods for affecting the survival or function of neurons by the administration of a polynucleotide encoding a truncated GDNF protein. Claims 31 and 45-49 are currently pending in the present application. Claims 31 and 45-49 are subject to restriction. In the two-layered restriction requirement, the Examiner divided the pending claims into the following groups:

<u>Group</u>	<u>Claims</u>	<u>Subject Matter</u>
I	31 and 45-49	A method for affecting survival or function of neurons comprising administering a polynucleotide encoding a truncated GDNF protein product.
II	31 and 45-49	A method comprising implanting in a patient a cell transformed with a polynucleotide encoding a truncated GDNF protein product to provide <i>in vivo</i> production of the truncated GDNF protein product.

Applicants elects the invention of Group I (Claims 31 and 45-49).

The Restriction Requirement under 35 U.S.C. § 121 also required election of one of the specific sequences, SEQ ID NOs: 3-38, 42, 44 referenced in the claims. Applicants have provisionally elected SEQ ID NO:18 with traverse.

Traverse of the second layer of the restriction requirement turns on the issue as to whether there would be a serious burden on the Examiner if restriction was not required. 35 U.S.C. §121 states that “[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions (emphasis added).” The statute, therefore, establishes restriction as a procedural matter within the discretion of the Patent and Trademark Office Director. M.P.E.P. § 803 provides Examiners with further guidance as to when restriction is proper. Section 803 states “[i]f the search and examination of an entire application can be made without serious burden, the examiner **must** examine it on the merits, even though it includes claims to independent or distinct inventions (emphasis added).”

The Examiner indicated that the restriction between each sequence was proper because “[e]ach sequence requires a separate search of the literature and sequence databases. A search and

examination of an Invention of as it pertains for all 39 sequences would therefore present the examiner with undue search burden (Office Action, Paper No. 4, page 5, paragraph 7)."

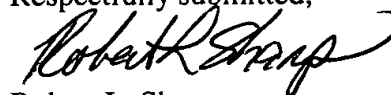
Applicants respectfully traverse the Restriction Requirement and request reconsideration and/or withdrawal thereof. Applicants contend that it would not be a serious burden on the Patent Office if restriction is not required amongst the sequence groups identified in the present Office Action because of the very close similarity between the polynucleotide sequences recited. Teachings on this type of closely related subject matter are readily identified with sequence based searches. The advanced state of bioinformatics and indexed sequence databases presently allows such searches to be rendered without unduly burdening the searching authority. A single well thought out search using any one of the closely related, albeit unique, sequences would be sufficient to identify the closest matching polynucleotides known in the art. In the present case, multiple searches of divergent fields would not be necessary for a thorough examination. One of the sequences could be searched and the output from that search would indicate the state of the art relevant to polynucleotides encoding truncated GDNF polypeptides.

On these facts, Applicants respectfully submit that the Examiner has failed to validly establish a prima facie case for restriction and has improperly restricted inventive subject matter into the numerous groups which would result in overlapping searches.

In conclusion, Applicants assert that the Examiner did not set forth reasons sufficient to impose the present restriction requirement on the present application. Therefore, Applicants respectfully traverse second layer of the present Restriction Requirement and request reconsideration and/or withdrawal thereof. So as to be fully responsive to the Restriction Requirement, Applicants hereby elect the invention of Group I (Claims 31 and 45-49). In addition, Applicants hereby provisionally elect with traverse, sequence group (p) wherein the invention pertains to SEQ ID NO:18.

Please send all future correspondence to:
U.S. Patent Operations/RLS
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

Respectfully submitted,



Robert L. Sharp
Attorney for Applicants
Registration No.: 45,609
Phone: (805) 447-5992
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